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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,377	01/13/2004	Randall W. Yatscoff	16594-004005	3631

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/757,377	Applicant(s) YATSCOFF ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/13/04.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-82 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 60-82 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ELECTION OF SPECIES

- 1)** Claims 1-59 have been canceled.
Claims 60-82 are under prosecution.
- 2)** The application contains claims directed to immunoassay kits that use the following patentably distinct individual or pleural antibody species of the claimed invention:

I. Individual antibody species:

- (a) antibody CSA-2G9;
- (b) antibody AM1-7F5;
- (c) antibody AM1-3B1;
- (d) antibody AM1-2E10;
- (e) antibody AM9-1-3C1;
- (f) antibody AM19-1-5D2;
- (g) antibody AM19-1-5B3;
- (h) antibody AM19-9-5A6;
- (i) antibody AM9-1-6D4;
- (j) antibody AM9-1-7D2;
- (k) antibody AM9-9-11G9;
- (l) antibody AM9-9-6C3;
- (m) antibody AM19-1-7E12;
- (n) antibody AM9-1-2A11;
- (o) antibody AM19-9-1E11;
- (p) antibody AM19-9-1D8;
- (q) antibody AM19-9-2G9;
- (r) antibody AM9-9-11H11;
- (s) antibody AM9-9-4F5;
- (t) AM9-1-4D6; and

II. Combination antibody species:

- (u) one first antibody and one second antibody combination independently selected from CSA-2G9; AM1-7F5; AM1-3B1; AM1-2E10; AM9-1-3C1; AM19-1-5D2; AM19-1-

5B3; antibody AM19-9-5A6; AM9-1-6D4; AM9-1-7D2; AM9-9-11G9; AM9-9-6C3; AM19-1-7E12; AM9-1-2A11; AM19-9-1E11; AM19-9-1D8; AM19-9-2G9; AM9-9-11H11; AM9-9-4F5; and AM9-1-4D6.

Each of these individual or pleural antibody species have different structural and biologic properties and divergent epitope specificities.

As per *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980), the initial examination will be limited to an immunoassay kit that uses one of the above-identified antibody species. While the immunoassay kits have common utility, each kit uses an antibody species that lacks substantial similarity in terms of structure and/or epitope specificities. As set forth above, there is a combination antibody species and an individual subcombination antibody species used in the claimed immunoassay kits. Applicants should note that upon examination of the elected subcombination antibody species, if the kit that uses that elected subcombination antibody species is found to be allowable, the Office would consider rejoining the combination of that particular subcombination species.

3) Applicants are required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

4) Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other invention.

5) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

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Art Unit: 1645
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6) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

July, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER